In re Application of: Shih et al

Serial No.: 09/431,519 Filed: November 1, 1999

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application (note that amendments are **highlighted in bold**):

Claim Listing

- Claim 1. (currently amended) An anabolic implant dual formulation composition comprising: (i) an immediate-release first formulation consisting essentially of an anabolic agent, and (ii) a controlled-release second formulation comprising an anabolic agent and a controlled-release agent, wherein said immediate-release formulation and said controlled-release formulation cooperate to effect said stimulation, and wherein said anabolic agent, which may be the same or different in each formulation, is selected from the group consisting of zeranol, estradiol, estradiol benzoate, testosterone, testosterone propionate, trenbolone, somatrophin, salbutamol, progesterone, trenbolone acetate, salts and derivatives and combinations thereof.
- Claim 2. (original) The implant composition of claim 1, wherein said immediaterelease formulation and said controlled-release formulation are present respectively in a weight ratio range 1:2 to 1:25 in said composition.
- Claim 3. (original) The implant composition of claim 1, wherein said immediaterelease formulation and said controlled-release formulation are present respectively in a weight ratio range 1:2 to 1:10 in said composition.
- Claim 4. (original) The implant composition of claim 1, wherein said immediaterelease formulation and said controlled-release formulation are present respectively in a weight ratio range 1:3 to 1:8 in said composition.
- Claim 5. (original) The implant composition of claim 1, wherein said composition is subcutaneously injectable in said cattle.

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Claim 6. (original) The implant composition of claim 1, wherein said immediaterelease formulation and said controlled-release formulation contain the same anabolic agent.

- Claim 7. (original) The implant composition of claim 1, wherein said immediaterelease formulation and said controlled-release formulation contain different anabolic agents.
- Claim 8. (currently amended) The implant composition of claim 1, wherein said anabolic agent <u>in either said immediate-release formulation or said controlled-release formulation</u> is selected from the group consisting of zeranol, estradiol, estradiol benzoate, trenbolone, trenbolone acetate, somatotrophin, testosterone, testosterone propionate, salbutamol, progesterone, and combinations, salts and derivatives thereof.
- Claim 9. (original) The implant composition of claim 8, wherein said anabolic agent is zeranol.
- Claim 10. (original) The implant composition of claim 8, wherein said anabolic agent is trenbolone acetate.
- Claim 11. (previously presented) The implant composition of claim 9, wherein said zeranol is the anabolic agent in both said immediate-release formulation and said controlled-release formulation and comprises from about 50 wt.% to about 95 wt.% of said composition based on the total weight of said implant composition.
- Claim 12. (previously presented) The implant composition of claim 9, wherein said zeranol is the anabolic agent in both said immediate-release formulation and said controlled-release formulation and comprises from about 60 wt.% to about 80 wt.% of said composition based on the total weight of said implant composition.

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Claim 13. (original) The implant composition of claim 1, wherein said immediaterelease formulation additionally contains a diluent.

Claim 14. (original) The implant composition of claim 13, wherein said diluent is selected from the group consisting of lactose, mannitol, sorbitol, sucrose, dextrose, starches, hydrolyzed starches, and combinations thereof.

Claim 15. (original) The implant composition of claim 14, wherein said diluent is lactose.

Claim 16. (original) The implant composition of claim 1, wherein said controlled-release agent is selected from the group consisting of poly(D,L-lactide-co-glycolide), ethyl cellulose, methyl acrylate-methyl methacrylate copolymer, methyl cellulose, hydroxyethyl cellulose, hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose, and combinations thereof.

Claim 17. (original) The implant composition of claim 16, wherein said controlled-release agent is poly(D,L-lactide-co-glycolide).

Claim 18. (original) The implant composition of claim 16, wherein said controlledrelease agent is ethyl cellulose.

Claim 19. (currently amended) The implant composition of claim 1, wherein said controlled-release agent comprises from about 1.0 wt.% to about 8.0 wt.% based on the total weight of said <u>dual formulation</u> implant composition.

Claim 20. (currently amended) The <u>dual formulation</u> implant composition of claim 1, further comprising a bulking agent, binder, excipient, tabletting agent, colorant and combinations thereof.

Claims 21-42 (canceled)